Form PTO-1449 Substitute **U.S. Department of Commerce**
Patent and Trademark Office

Application Number	10/797,749
Filing Date	January 28, 2004
First Named Inventor	Ira Tabas
Art Unit	1647
Examiner Name	B.E. Bunner
Attorney Docket No.	0575/60921-A/JPW/MVM

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
/BEB/	1	US 09/553,927	04-21-2000	Tabas et al.
/BEB/	2	US 2003-0235878 A1	12-25-2003	Tabas et al.
/BEB/	70	US 2002-0128266 A1	09-12-2002	Campbell et al.
/BEB/	71	US 2002-0146681 A1	10-10-2002	Rothblat

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
/BEB/	3	WO 2001/080715 A3	11-01-2001	The Trustees of Columbia University in the City of New York	
/BEB/	4	WO 2003/092467 A3	11-13-2003	The Trustees of Columbia University in the City of New York	

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/BEB/	5	December 22, 2006 International Preliminary Examination Report issued in connection with PCT International Application No. PCT/US2001/12877, filed April 20, 2001	
	6	Aikawa, K., et al. (1994) "Structure-specific Inhibition of Lysosomal Cholesterol Transport in Macrophages by Various Steriods," *Biochim. Biophys. Acta* 1213: 127-134	
/BEB/	7	Arends, M.J., et al. (1991) "Apoptosis: Mechanisms and Roles in Pathology," *Int. Rev. Exper. Pathol.* 32: 223-254	
/BEB/	8	Basu, S.K., et al. (1976) "Degradation of Cationized Low Density Lipoprotein and Regulation of Cholesterol Metabolism in Homozygous Familial Hypercholesterolemia Fibroblasts," *Proc. Natl. Acad. Sci. U.S.A.* 73: 3178-3182	
/BEB/	9	Bertolotti, A., et al. (2000) "Dynamic Interaction of BiP and ER Stress Transducers in the Unfolded-protein Response," *Nat. Cell Biol.* 2: 326-332	
/BEB/	10	Bjorkhem, I., et al. (1994) "Atherosclerosis and Sterol 27-Hydroxylase: Evidence for a Role of This Enzyme in Elimination of Cholesterol From Human Macrophages," *Proc. Natl. Acad. Sci. U.S.A.* 91: 8592-8596	
/BEB/	11	Brown, M.S., et al. (1983) "Lipoprotein Metabolism in the Macrophage: Implications for Cholesterol Deposition in Atherosclerosis[1]," *Annu. Rev. Biochem.* 52: 223-261	
/BEB/	12	Brown, M.S., et al. (1997) "The SREBP Pathway: Regulation of Cholesterol Metabolism by Proteolysis of a Membrane-Bound Transcription Factor," *Cell* 89: 331-340	
/BEB/	13	Calfon, M., et al. (2002) "IRE1 Couples Endoplasmic Reticulum Load to Secretory Capacity by Processing the *XBP-1* mRNA," *Nature* 415: 92-96	
/BEB/	14	Chang, M.-K., et al. (1999) "Monoclonal Antibodies Against Oxidized Low-density Lipoprotein Bind to Apoptotic Cells and Inhibit Their Phagocytosis by Elicited Macrophages: Evidence that Oxidation-specific Epitopes Mediate Macrophage Recognition," *Proc. Natl. Acad. Sci. U.S.A.* 96: 6353-6358	
/BEB/	15	Devlin, C., et al. (2002) "Genetic Alterations of IL-1 Receptor Antagonist in Mice Affect Plasma Cholesterol Level and Foam Cell Lesion Size," *Proc. Natl. Acad. Sci. U.S.A.* 99: 6280-6285	

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	~~16~~	~~FENG, B., et al. (2003) "The Endoplasmic Reticulum is the Site of Cholesterol-induced Cytotoxicity in Macrophages," *Nat. Cell Biol.* 5: 781-792~~	
/BEB/	17	FENG, B., et al. (2003) "Niemann-Pick C Heterozygosity Confers Resistance to Lesional Necrosis and Macrophage Apoptosis in Murine Atherosclerosis," *PNAS* 100: 10423-10428	
/BEB/	18	Fuster, V., et al. (1992) "The Pathogenesis of Coronary Artery Disease and the Acute Coronary Syndromes: (First of Two Parts)," *N. Engl. J. Med.* 326: 242-250	
/BEB/	19	Graham, J.M., et al. (1970) "The Properties of Mitochondria Enriched *in vitro* with Cholesterol," *Eur. J. Biochem.* 12: 58-66	
/BEB/	20	Green, D.R. (1998) "Apoptotic Pathways: The Roads to Ruin," *Cell* 94: 695-698	
/BEB/	21	Guyton, J.R., et al. (1996) "Development of the Lipid-Rich Core in Human Atherosclerosis," *Arterioscler. Thromb. Vase. Biol.* 16: 4-11	
/BEB/	22	Harding, H.P., et al. (1999) "Protein Translation and Folding are Coupled by an Endoplasmic-reticulum-resident Kinase," *Nature* 397: 271-274	
/BEB/	23	Harding, H.P., et al. (2000) "*Perk* is Essential for Translational Regulation and Cell Survival during the Unfolded Protein Response," *Mol. Cell* 5: 897-904	
/BEB/	24	Harding, H.P., et al. (2000) "Regulated Translation Initiation Controls Stress-Induced Gene Expression in Mammalian Cells," *Mol. Cell* 6: 1099-1108	
/BEB/	25	Harding, H.P., et al. (2001) "Diabetes Mellitus and Exocrine Pancreatic Dysfunction in *Perk-I-* Mice Reveals a Role for Translational Control in Secretory Cell Survival," *Mol. Cell* 7: 1153-1163	
/BEB/	26	Kockx, M.M., et al. (1998) "RNA Synthesis and Splicing Interferes with DNA *in Situ* End Labeling Techniques Used to Detect Apoptosis," *Am. J. Pathol.* 152: 885-888	
/BEB/	27	Kockx, M.M. (1998) "Apoptosis in the Atherosclerotic Plaque: Quantitative and Qualitative Aspects," *Arterioscler. Thromb. Vase. Biol.* 18: 1519-1522	

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/BEB/	28	Kruth, H.S. (1985) "Subendothelial Accumulation of Unesterified Cholesterol: An Early Event in Atherosclerotic Lesion Development," *Atherosclerosis* 57: 337-341	
/BEB/	29	Kruth, H.S., et al. (1986) "Type C Niemann-pick Disease: Abnormal Metabolism of Low Density Lipoprotein in Homozygous and Heterozygous Fibroblast*," *J. Biol. Chem.* 261: 16769-16774	
/BEB/	30	Lemasters, J. J. (1999) "Mechanisms of Hepatic Toxicity V. Necrapoptosis and the Mitochondrial Permeability Transition: Shared Pathways to Necrosis and Apoptosis*," *Am. J. Physiol.* 276: G1-G6	
/BEB/	31	Liscum, L., et al. (1992) "Intracellular Cholesterol Transport," *J. Lipid Res.* 33: 1239-1254	
/BEB/	32	Lopes-Virella, M.F., et al. (1992) "Immune Mechanisms of Atherosclerosis in Diabetes Mellitus," *Diabetes* 41 (Suppl. 2): 86-91	
/BEB/	33	Majno, G., et al. (1995) "Apoptosis, Oncosis, and Necrosis: An Overview of Cell Death," *Am. J. Pathol.* 146: 3-15	
/BEB/	34	Matsuda, K. (1994) "ACAT Inhibitors as Antiatherosclerotic Agents: Compounds and Mechanisms," *Med. Res. Rev.* 14: 271-305	
/BEB/	35	Maxfield, F.R. (2002) "Intracellular Cholesterol Transport," *J. Clin. Invest.* 110: 891-898	
/BEB/	36	McCullough, K.D., et al. (2001) "Gadd153 Sensitizes Cells to Endoplasmic Reticulum Stress by Down-Regulating Bc12 and Perturbing the Cellular Redox State," *Mol. Cell Biol.* 21: 1249-1259	
/BEB/	37	Nakagawa, T., et al. (2000) "Caspase-12 Mediates Endoplasmic-reticulum-specific Apoptosis and Cytotoxicity by Amyloid-β," *Nature* 403: 98-103	
/BEB/	38	Nakashima, Y., et al. (1994) "ApoE-Deficient Mice Develop Lesions of All Phases of Atherosclerosis Throughout the Arterial Tree," *Arterioscler. Thromb.* 14: 133-140	
/BEB/	39	Nishitoh, H., et al. (2002) "ASK1 is Essential for Endoplasmic Reticulum Stress-induced Neuronal Cell Death Triggered by Expanded Polyglutamine Repeats," *Genes Dev.* 16: 1345-1355	

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/BEB/	40	Oyadomari, S., et al. (2002) "Targeted Disruption of the *Chop* Gene Delays Endoplasmic Reticulum Stress-mediated Diabetes," *J. Clin. Invest.* 109: 525-532	
/BEB/	41	Papahadjopoulos, D. (1974) "Cholesterol and Cell Membrane Function: A Hypothesis Concerning the Etiology of Artherosclerosis," *J. Theor. Biol.* 43: 329-337	
/BEB/	42	Patil, C., et al. (2001) "Intracellular Signaling from the Endoplasmic Reticulum to the Nucleus: The Unfolded Protein Response in Yeast and Mammals," *Curr. Opin. Cell Biol.* 13: 349-356	
/BEB/	43	Pentchev, P.G., et al. (1984) "A Genetic Storage Disorder in BALB/C Mice with a Metabolic Block in Esterification of Exogenous Cholesterol*," *J. Biol. Chem.* 259: 5784-5791	
/BEB/	44	Pentchev, P.G., et al. (1997) "Biological Implications of the Niemann-Pick C Mutation," *Sub-Cell. Biochem.* 28: 437-451	
/BEB/	45	Reddick, R.L., et al. (1994) "Atherosclerosis in Mice Lacking Apo E: Evaluation of Lesional Development and Progression," *Arterioscler. Thromb.* 14: 141-147	
/BEB/	46	Ross, A.C., et al. (1984) "Selective Inhibition of Acyl Coenzyme A: Cholesterol Acyltransferase by Compound 58-035*," *J. Biol. Chem.* 259: 815-819	
/BEB/	47	Ross, D.D., et al. (1989) "Estimation of Cell Survival by Flow Cytometric Quantification of Fluorescein Diacetate/Propidium Iodide Viable Cell Number[1]," *Cancer Res.* 49: 3776-3782	
/BEB/	48	Small, D.M., et al. (1984) "Physicochemical and Histological Changes in the Arterial Wall of Nonhuman Primates during Progression and Regression of Atherosclerosis," *J. Clin. Invest.* 73: 1590-1605	
/BEB/	49	Smith, J. D., et al. (1995) "Decreased Atherosclerosis In Mice Deficient In Both Macrophage Colony-stimulating Factor (*op*) and Apoliprotein E," *Proc. Natl. Acad. Sci. U.S.A.* 92: 8264-8268	
/BEB/	50	Tabas, I., et al. (1988) "Rabbit Liver Microsomal ACAT: Smooth ER Enzyme Associated With A Lipid ACAT Inhibitor," *Arteriosclerosis* 8: 559A	
/BEB/	51	Tang, W.A., et al. (1999) "Macrophage-targeted CTP: Phosphocholine Cytidylyltransferase (1-314) Transgenic Mice," *Biochim. Biophys. Acta* 1437: 301-316	

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/BEB/	52	Travers, K.J., et al. (2000) "Functional and Genomic Analyses Reveal an Essential Coordination between the Unfolded Protein Response and ER-Associated Degradation," *Cell* 101: 249-258	
/BEB/	53	Treiman, M. (2002) "Regulation of the Endoplasmic Reticulum Calcium Storage During the Unfolded Protein Response-Significance in Tissue Ischemia?" *Trends Cardiovasc. Med.* 12: 57-62	
/BEB/	54	Urano, F., et al. (2000) "Coupling of Stress in the ER to Activation of JNK Protein Kinases by Transmembrane Protein Kinases IRE1," *Science* 287: 664-666	
/BEB/	55	Wang, X.Z., et al. (1996) "Stress-Induced Phosphorylation and Activation of the Transcription Factor CHOP (GADD153) by p38 MAP Kinase," *Science* 272: 1347-1349	
/BEB/	56	Warner, G.J., et al. (1995) "Cell Toxicity Induced by Inhibition of Acyl Coenzyme A: Cholesterol Acyltransferase and Accumulation of Unesterified Cholesterol*," *J. Biol. Chem.* 270: 5772-5778	
/BEB/	57	Yoshida, H. (2001) "XBP1 mRNA is Induced by ATF6 and Spliced by IRE1 in Response to ER Stress to Produce a Highly Active Transcription Factor," *Cell* 107: 881-891	
/BEB/	58	Zhang, C., et al. (1998) "A Cell Surface Receptor Defined by a mAb Mediates A Unique Type of Cell Death Similar to Oncosis," *Proc. Natl. Acad. Sci. U.S.A.* 95: 6290-6295	
/BEB/	59	Zhang, P., et al. (2002) "The PERK Euraryotic Initiation Factor 2α Kinase Is Required for the Development of Sketetal System, Postnatal Growth, and the Function and Viability of the Pancreas," *Mol. Cell Biol.* 22: 3864-3874	
/BEB/	60	Zinszner, H., et al. (1998) "CHOP is Implicated in Programmed Cell Death in Response to Impaired Function of the Endoplasmic Reticulum," *Genes Dev.* 12: 982-995	
/BEB/	61	May 7, 2001 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 09/553,927	
/BEB/	62	March 8, 2002 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 09/553,927	
/BEB/	63	September 9, 2002 Advisory Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 09/553,927	

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/BEB/	64	July 29, 2003 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 09/553,927	
/BEB/	65	September 21, 2005 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 10/426,415	
/BEB/	66	March 24, 2006 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 10/426,415	
/BEB/	67	October 4, 2006 Office Action issued by the United States Patent and Trademark Office in connection with U.S. Application Serial No. 10/426,415	
/BEB/	68	December 19, 2003 PCT International Search Report in connection with PCT International Application No. PCT/US2001/012877, filed April 20, 2001, publication No. WO/2001/080715 A3, published November 1, 2001 on behalf of The Trustees of Columbia University in the City of New York	
/BEB/	69	March 15, 2004 PCT International Search Report issued in connection with PCT International Application No. PCT/US2003/013164, filed April 30, 2003 on behalf of The Trustees of Columbia University in the City of New York	
/BEB/	72	Atger, V.M., et al. (1997) "Cyclodextrins as catalysts for the removal of cholesterol from macrophage foam cells," *J. Clin. Invest.* 99: 773-780	
/BEB/	73	Braganza, D.M., et al. (2001) "New insights into atherosclerotic plaque rupture," *Postgrad. Med. J.* 77: 94-98	
/BEB/	74	Buton, X., et al. (1999) "Unique cellular events occurring during the initial interaction of macrophages with matrix-retained or methylated aggregated low density lipoprotein (LDL)," *J. Biol. Chem.* 274: 32112-32121	
/BEB/	75	Chang, et al. (1995) "Inhibition of hypercholestemia-induced atherosclerosis in the nonhuman primate by probucol," *Arterioscler Thromb. Vasc. Biol.* 15: 1631-1640	
/BEB/	76	Higgins, M.E., et al. (1999) "Niemann-pick C1 is a late endosome-resident protein that transiently associates with lysosomes and the transgolgi network," *Molec. Genet. Metab.* 68: 1-13	

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/BEB/	77	Neufeld, E.B., et al. (1999) "The Niemann-pick C1 protein resides in a vesicular compartment linked to retrograde transport of multiple lysosomal cargo," *J. Biol. Chem.* 274: 9627-9635	
/BEB/	78	Rabbani, R., et al. (1999) "Strategies to achieve coronary arterial plaque stabilization," *Cardiovasc. Res.* 41: 402-417	
/BEB/	79	Simons, K., et al. (2000) "How cells handle cholesterol," *Science* 290: 1721-1726	
/BEB/	80	Watari, H., et al. (2000) "NPC1-containing compartment of human granulosa-lutein cells: a role in the intracellular trafficking of cholesterol supporting steriodogenesis," *Exp. Cell Res.* 255: 56-66	
/BEB/	81	Travis, A.J., et al. (2002) "The role of cholesterol efflux in regulating the fertilization potential of mammalian spermatozoa," *J. Clin. Invest.* 110: 731-736	
/BEB/	82	Smith, J.D., et al. (1996) "Cuclic AMP induces apolipoprotein E binding activity and promotes cholesterol efflux from a macrophage cell line to apolipoprotein acceptors," *J. Biol. Chem.* 271: 30647-30655	
/BEB/	83	Kilsdonk, E.P., et al. (1995) "Cellular cholesterol efflux mediated by cyclodextrins," *J. Biol. Chem.* 270: 17250-17256	
/BEB/	84	Merriam-Webster Medline Plus online medical dictionary definition of "apolipoprotein," http://www.nlm.nih.gov/medlineplus/mplusdictionary.html, accessed online September 25, 2006, 1 page	
/BEB/	85	Carstea, E.D., et al. (1997) "Niemann-Pick C1 disease gene: homology to mediators of cholesterol homeostasis," *Science* 277: 228-231	
/BEB/	86	Mitchinson, M.J., et al. (1996) "Hardwick, and M.R. Bennett. Cell death in atherosclerotic plaques," *Curr. Opin. Lipidol.* 7: 324-329	
/BEB/	87	Ball, R.Y., et al. (1995) "Evidence that the death of macrophage foam cells contributes to the lipid core of atheroma," *Atherosclerosis* 114: 45-54	
/BEB/	88	Bauriedel, G. et al. (1999) "Apoptosis and Its Regulation in Acute Coronary Syndrom Lesions," *Circulation (Supp. I)* 100: I-542, Abstract 2855	

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	89	Tabas, I. (1997) "Free cholesterol-induced cytotoxicity. A possible contributing factor to macrophage foam cell necrosis in advanced atherosclerotic lesions," *Trends Cardiovasc. Med.* 7: 256-263	
/BEB/	90	Tabas, I. et al. (1996) "Evidence that the initial up-regulation of phosphatidylcholine biosynthesis in free cholesterol-loaded macrophages is an adaptive response that prevents cholesterol-induced cellular necrosis. Proposed role of an eventual failure of this response in foam cell necrosis in advanced atherosclerosis," *J. Biol. Chem.* 271: 22773-22781	
/BEB/	91	Liscum, L. et al. (1998) "Niemann-Pick disease type C," *Curr. Opin. Lipidol.* 9: 131-135.	
/BEB/	92	Loftus, S.K., et al., (1997) "Murine model of Niemann-Pick C disease: mutation in a cholesterol homeostasis gene," *Science* 277: 232-235	
/BEB/	93	Shiratori, Y., et al. (1994) "Free cholesterol loading of macrophages stimulates phosphatidylcholine biosynthesis and up-regulation of CTP:phosphocholine cytidylyltransferase," *J. Biol. Chem.* 269: 11337-11348	
/BEB/	94	Aiello, R.J. et al. (2002) "Increased atherosclerosis in hyperlipidemic mice with inactivation of ABCA1 in macrophages," *Arterioscler. Thromb. Vasc. Biol.* 22(4): 630-37	
/BEB/	95	Arakawa R., et al. (2002) "Helical apolipoproteins stabilize ATP-binding cassette transporter A1 by protecting it from thiol protease-mediated degradation," *J. Biol. Chem.* 277: 22426-22429	
/BEB/	96	Attie, A.D., et al. (2001) "Pivotal role of ABCA1 in reverse cholesterol transport influencing HDL levels and susceptibility to atherosclerosis," *J. Lipid Res.* 42: 1717-1726	
/BEB/	97	Berberian, P.A., et al. (1990) "Immunohistochemical localization of heat shock protein-70 in normal-appearing and atherosclerotic specimens of human arteries," *Am. J. Path.* 136: 71-80	
/BEB/	98	Bretscher, M.S., et al. (1993) "Cholesterol and the Golgi apparatus," *Science* 261: 1280-1281	

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		First Named Inventor	Ira Tabas
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	99	Chen W., et al. (2001) "Preferential ATP-binding cassette transporter A1-mediated cholesterol efflux from late endosomes/lysosomes," *J. Biol. Chem.* 276: 43564-43569	
/BEB/	100	Christian, A.E., et al. (1997) "Use of cyclodextrins for manipulating cellular cholesterol content," *J. Lipid Res.* 38: 2264-2272	
/BEB/	101	Costet, P. et al. (2000) "Sterol-dependent transactivation of the ABC1 promoter by the liver X receptor/retinoid X receptor," *J. Biol. Chem.* 275: 28240-28245	
/BEB/	102	Fazio, S., et al. (2001) "Increased atherosclerosis in LDL receptor-null mice lacking ACAT1 in macrophages," *J. Clin. Invest.* 107: 163-71	
	103	Feng, B., et al. (2002) "ABCA1-mediated cholesterol efflux is defective in free cholesterol-loaded macrophages. Mechanism involves enhanced ABCA1 degradation in a process requiring full NPC1 activity," *J. Biol. Chem.* 277: 43271-43280	
/BEB/	104	Haghpassand M., et al. (2001) "Monocyte/macrophage expression of ABCA1 has minimal contribution to plasma HDL levels," *J. Clin. Invest.* 108: 1315-1320	
/BEB/	105	Joyce C.W., et al. (2002) "The ATP binding cassette transporter A1 (ABCA1) modulates the development of aortic atherosclerosis in C57BL/6 and apoE-knockout mice," *Proc. Natl. Acad. Sci. U. S. A.* 99: 407-412	
/BEB/	106	Kellner-Weibel, G., et al. (1999) "Cytotoxic cholesterol is generated by the hydrolysis of cytoplasmic cholesteryl ester and transported to the plasma membrane," *Atherosclerosis* 146: 309-319	
	107	Kellner-Weibel, G., et al. (1998) "Effects of intracellular free cholesterol accumulation on macrophage viability: a model for foam cell death," *Arterioscler. Thromb. Vasc. Biol.* 18: 423-431	
/BEB/	108	Khan, N., et al. (2003) "Plasma membrane cholesterol: A possible barrier to intracellular oxygen in normal and mutant CHO cells defective in cholesterol metabolism," *Biochemistry* 42: 23-29	

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/BEB/	109	Kolodgie, F.D., et al. (2000) "Localization of apoptotic macrophages at the site of plaque rupture in sudden coronary death," *Am. J. Pathol.* 157: 1259-1268	
/BEB/	110	Kruth, H.S., et al. (1984) "Histochemical detection and differentiation of free and esterified cholesterol in swine atherosclerosis using filipin," *Exp. Mol. Pathol.* 40: 288-294	
/BEB/	111	Lange, Y., et al. (1997) "Quantitation of the pool of cholesterol associated with acyl-CoA:cholesterol acyltransferase in human fibroblasts," *J. Biol. Chem.* 272: 13103-13108	
/BEB/	112	Lange, Y., et al. (2000) "Cholesterol movement in Niemann-Pick Type C cells and in cells treated with amphiphiles," *J. Biol. Chem.* 275: 17468-17475	
/BEB/	113	Lange, Y., et al. (1997) "The fate of cholesterol exiting lysosomes," *J. Biol. Chem.* 272: 17018-17022	
/BEB/	114	Lange, Y. (1992) "Tracking cell cholesterol with cholesterol oxidase," *J. Lipid Res.* 33: 315-321	
/BEB/	115	Leventhal A.R., et al. (2001) "Acid sphingomyelinase-deficient macrophages have defective cholesterol trafficking and efflux," *J. Biol. Chem.* 276: 44976-44983	
/BEB/	116	Libby, P., et al. (1993) "The role of macrophages in atherogenesis," *Curr. Opin. Lipidol.* 4: 355-363	
	~~117~~	~~Liscum, L., et al. (1998) "Niemann-Pick disease type C," *Curr. Opin. Lipidol.* 9: 131-135~~	
/BEB/	118	Lundberg, B. (1985) "Chemical composition and physical state of lipid deposits in atherosclerosis," *Atherosclerosis* 56: 93-110	
/BEB/	119	Mallat, Z., et al. (1999) "Shed membrane microparticles with procoagulant potential in human atherosclerotic plaques: a role for apoptosis in plaque thrombogenicity," *Circulation* 99: 348-353	
/BEB/	120	Marathe S., et al. (1998) "Human vascular endothelial cells are a rich and regulatable source of secretory sphingomyelinase. Implications for early atherogenesis and ceramide-mediated cell signaling," *J. Biol. Chem.* 273: 4081-4088	

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	121	Mitchinson, M.J., et al. (1996) "Cell death in atherosclerotic plaques," *Curr. Opin. Lipidol.* 7: 324-329	
/BEB/	122	Rapp, J.H., et al. (1983) "Lipids of human atherosclerotic plaques and xanthomas: clues to the mechanism of plaque progression," *J. Lipid Res.* 24: 1329-1335	
/BEB/	123	Ross, R. (1995) "Cell biology of atherosclerosis," *Annu. Rev. Physiol.* 57: 791-804	
/BEB/	124	Schissel, S.L., et al. (1998) "Secretory sphingomyelinase, a product of the acid sphingomyelinase gene, can hydrolyze atherogenic lipoproteins at neutral pH. Implications for atherosclerotic lesion development," *J. Biol. Chem.* 273: 2738-2746	
	125	Mitchinson, M.J., et al. (1996) "Cell death in atherosclerotic plaques," *Curr. Opin. Lipidol.* 7: 324-329	
/BEB/	126	Sparrow, S.M., et al. (1999) "U18666A inhibits intracellular cholesterol transport and neurotransmitter release in human neuroblastoma cells," *Neurochem Res.* 24: 69-77	
/BEB/	127	Tabas, I. (2000) "Cholesterol and phospholipid metabolism in macrophages," *Biochim. Biophys. Acta* 1529: 164-174	
/BEB/	128	Tabas, I. (2002) "Consequences of cellular cholesterol accumulation: basic concepts and physiological implications," *J. Clin. Invest.* 110: 905-911	
/BEB/	129	Tall, A.R. (1998) "An overview of reverse cholesterol transport," *Eur. Heart J.* A31-A35	
/BEB/	130	Trogan, E., et al. (2002) "Laser capture microdissection analysis of gene expression in macrophages from atherosclerotic lesions of apolipoprotein E-deficient mice," *Proc. Natl. Acad. Sci. U.S.A.* 99: 2234-2239	
/BEB/	131	Underwood, K.W., et al. (1998) "Evidence for a cholesterol transport pathway from lysosomes to endoplasmic reticulum that is independent of the plasma membrane," *J. Biol. Chem.* 273: 4266-4274	

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/BEB/	132	Underwood, K.W., et al. (1996) "Quantitative analysis of hydrophobic amine inhibition of intracellular cholesterol transport," *J. Lipid Res.* 37: 1556-1568	
/BEB/	133	Vaisman, B.L., et al. (2001) "ABCA1 overexpression leads to hyperalphalipoproteinemia and increased biliary cholesterol excretion in transgenic mice," *J. Clin. Invest.* 108: 303-309	
/BEB/	134	van Eck, M., et al. (2002) "Leukocyte ABCA1 controls susceptibility to atherosclerosis and macrophage recruitment into tissues," *Proc. Natl. Acad. Sci. U.S.A.* 99: 6298-6303, E-published 2002 Apr 23	
/BEB/	135	Wang, Y., et al. (2002) "Unsaturated fatty acids inhibit cholesterol efflux from macrophages by increasing degradation of ATP-binding cassette transporter A1," *J. Biol. Chem.* 277: 5692-5697	
/BEB/	136	Williams, K.J., et al. (1995) "A reexamination of the NRMP matching algorithm. National Resident Matching Program," *Arterioscler. Thromb. Vasc. Biol.* 15: 551-561	
/BEB/	137	Yancey, P.G., et al. (1996) "Cellular cholesterol efflux mediated by cyclodextrins. Demonstration Of kinetic pools and mechanism of efflux," *J. Biol. Chem.* 271: 16026-16034	
/BEB/	138	Yao, P.M., et al. (2000) "Free cholesterol loading of macrophages induces apoptosis involving the fas pathway," *J. Biol. Chem.* 275: 23807-23813	
/BEB/	139	Yao, P.M., et al. (2001) "Free cholesterol loading of macrophages is associated with widespread mitochondrial dysfunction and activation of the mitochondrial apoptosis pathway," *J. Biol. Chem.* 276: 42468-42476	
/BEB/	140	Yeagle, P.L. (1991) "Modulation of membrane function by cholesterol," *Biochimie* 73: 1303-1310	
/BEB/	141	Zhang, D., et al. (2000) "Macrophages deficient in CTP:Phosphocholine cytidylyltransferase-alpha are viable under normal culture conditions but are highly susceptible to free cholesterol-induced death. Molecular genetic evidence that the induction of phosphatidylcholine biosynthesis in free cholesterol-loaded macrophages is an adaptive response," *J. Biol. Chem.* 275: 35368-35376	
/BEB/	142	Kapczinski, F., et al. (2003) "Antidepressants for generalized anxiety disorder," *Cochrane Databse Syst. Rev.* 2003:CD003592, abstract	

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